Mui Scientific Division of H&A Mui Enterprises Inc.
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September 27, 1999

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Dockets Management Branch (HFA – 305)
FDA
5630 Fishers Lane
Room 1061
Rockville, MD 20852
U.S.A.

Re: Docket Number 98N-1215

Dear Sir/Madam:

Mui Scientific is a Canadian minority-owned small business with only an annual total sales of $1 million. We have been in business since 1979 and 70% of our revenue comes from exports to Europe and the United States.

Since 1982, we have registered with the FDA both our establishment and our Medical Device Listing. Being a small company, we have only one person, the Operations Manager, also functioning as the Regulatory Affairs Manager, who knowledgeably and efficiently has handled all responsibilities related to the FDA all these years. She also acts as the official correspondent.

We fully agree with FDA's reasoning for Foreign Establishment Registration and Device Listings. However, we raise concerns about FDA's requirement for foreign establishments to utilize an "United States agent". Firstly, we will have difficulty finding an existing U.S. business associate in the form of an individual or a firm to help us out as our own U.S. agent since this position will be still rather time-occupying. Apart from this, there is the issue of "Confidentiality" on Mui Scientific's business information involved. Secondly, if we were to hire an U.S. independent "regulatory affair" firm to be our U.S. agent, we are afraid of the costs of the service. Seeing this FDA ruling as a compulsary requirement, the U.S. "regulatory affair" firms will no doubt charge high fees for their services. Mui Scientific is already paying high annual fees to maintain our ISO-9002 International Quality System registration and EC Mark/Medical Device Directive registration for exporting to Europe.

Also, in either scenarios almost duplicated amounts of time will have to be spent by, first, Mui Scientific providing the U.S. agent all detailed FDA requested information and then, second, for the U.S. agent to report to FDA. In addition, experiences have shown that a "middle-man" agent who does not know well the business operations of his clients, will tend to misunderstand and misinterpret general and even critical information given by the clients to the FDA.

Mui Scientific realizes that the FDA, in dealing with Foreign establishments in Europe, Asia and Africa etc. would find it more convenient to

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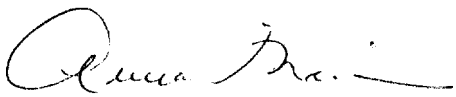
work with these establishments' U.S. based agents due to their long distances and foreign languages. However, Canada is U.S.'s English speaking next door neighbour. We would propose that Canada be exempted from this requirement. Besides, NAFTA has long recognized Canada as a brotherly neighbour who has been given special treatments.

Mui Scientific sincerely hopes that the FDA would take our comments into consideration.

Thank you.

Truly,



Anna Mui
Operations & Regulatory Affairs Manager

Cc: Birgit Mattiesen, Canadian Embassy
Debbie Walker, Ontario Exports Inc.

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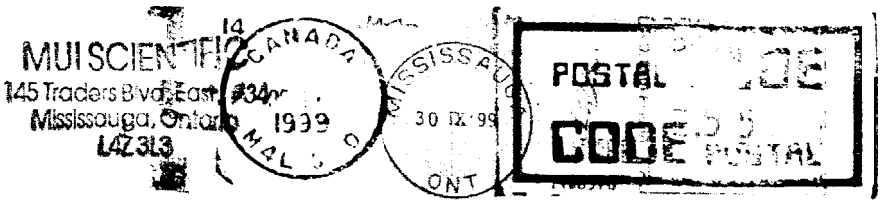

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